UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
**Antimicrobials Division**

**April 29, 2004**

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF:**
**Oscar**

**DP Barcode: D298992** **Reg. No. Or File Symbol: 4822-LGO**
**TGAI/MUP** **[]** OR **End-use Product [X]**

**TO:** Adam Heyward/Lisa McKelvin
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4/29/04

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**Product Formulation for Oscar from label**

| **Active Ingredient(s)** | **% by wt.** |
|---|---|
| Lactic acid | 2.0 % |

**BACKGROUND:**

The registrant has submitted a product chemistry package in support of a new registration of an end-use product to be used as a bathroom cleaner, sanitizer, and mildewstat. The package contains Confidential Statements of Formula, a label, and studies that have been submitted to and identified by the Agency as MRID's 46182801 and 46182802.

**FINDINGS:**

1. The concentration of the active ingredient on the Confidential Statements of Formula (CSFs dated Dec 12, 2003) is consistent with the label declaration; however, the label of the source of the active ingredient declares the active ingredient as "L-lactic acid." The CSF and the label of the end-use product both declare the active ingredient as "lactic acid" when the active ingredient on the label and CSF must be declared as "L-lactic acid." Until that clarification is made, the CSF is **unacceptable**.

2. All ingredients in the formulation are not cleared for use in pesticides. The registrant needs to have the supplier of Takasago RO-3136 contact the third party supplier in the Netherlands so that they can send the composition of that component directly to the Agency. This information must be typed on manufacturer letterhead and must contain the product name, manufacturer name/address and complete chemical composition including the chemical name, CAS Reg. No. and percentage by weight for each component of the mixture.

3. The descriptions of the starting materials and the manufacturing\production\formulation process are **unacceptable** until the CSF is accepted.

4. The discussion of the formation of impurities is will be **acceptable** when the CSF is accepted.

5. The preliminary analysis will be **acceptable** when the CSF is accepted.

6. The certified limits will be **acceptable** when the CSF is accepted.

7. The analytical enforcement method is **unacceptable**. The method submitted is for lactic acid and not for L-lactic acid.

8. The color, physical state, and odor of the product will be **acceptable** when the CSF is accepted. The product is a clear and colorless liquid with a characteristic odor of the solvent.

9. The density of the product is **unacceptable**. The CSF must be consistent with the lab report. The CSF states that the density 1.005 g/mL, but the lab report declares the density as 1.003 g/mL at 23 °C.

10. The pH of the product will be **acceptable** when the CSF is accepted. The pH is 2.4 at 22 °C.

11. The oxidation/reduction potential will be **acceptable** when the CSF is accepted. This property is not applicable to the product as it does not contain any oxidizing or reducing agents.

12. The flammability of the product will be **acceptable** when the CSF is accepted. The flame was extinguished at 77 °C and no flash point was observed in the test that was conducted using ASTM D-56.

13. The explodability of the product will be **acceptable** when the CSF is accepted. This property is not applicable to the product as it does not contain any explosive components.

14. The year-long study on storage stability and corrosion characteristics will be **acceptable** when they are submitted to the Agency. These properties will be evaluated in a separate study. Results are expected upon completion of the study.

15. The viscosity of the product will be **acceptable** when the CSF is accepted. The viscosity of the product is 1.6 cP at 25 °C at 1.1 cP at 50 °C.

16. The miscibility of the product will be **acceptable** when the CSF is accepted. This property is not applicable to the product as the product is not intended to be diluted with petroleum solvents.

17. The dielectric breakdown voltage of the product will be **acceptable** when the CSF is accepted. This property is not applicable to the product as the product is not for use in and around electrical equipment.

18. On an alternate formulation, "RO-3136" is duplicated on the CSF. This duplication must be corrected.

**RECOMMENDATIONS:**

1. Product Science Branch of Antimicrobials Division finds this submission in support of the registration of 4822-LGO to be unacceptable for the reasons stated in the findings. The registrant must correct the discrepancies discussed in the findings for registration to proceed.